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**Datasheet for the decision  
of 9 April 2014**

**Case Number:** T 0405/13 - 3.4.02

**Application Number:** 03077709.8

**Publication Number:** 1394535

**IPC:** G01N27/327, C12Q1/00

**Language of the proceedings:** EN

**Title of invention:**

Meter with rapid response glucose sensor

**Patent Proprietor:**

Diabetes Diagnostics, Inc.

**Opponents:**

Roche Diagnostics GmbH  
ARKRAY, Inc.

**Headword:**

**Relevant legal provisions:**

EPC Art. 56

**Keyword:**

Inventive step - (no) -  
putting into practice the closest prior art device leads to a  
device falling under claim 1 (point 2.3)

**Decisions cited:**

T 0408/12, T 0315/97

**Catchword:**



**Beschwerdekammern  
Boards of Appeal  
Chambres de recours**

European Patent Office  
D-80298 MUNICH  
GERMANY  
Tel. +49 (0) 89 2399-0  
Fax +49 (0) 89 2399-4465

Case Number: T 0405/13 - 3.4.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.4.02**  
**of 9 April 2014**

**Appellant:** Diabetes Diagnostics, Inc.  
(Patent Proprietor) 51 Sawyer Road,  
Suite 150  
Waltham, MA 02453 (US)

**Representative:** Brunner, John Michael Owen  
Carpmaels & Ransford LLP  
One Southampton Row  
London WC1B 5HA (GB)

**Appellant:** Roche Diagnostics GmbH  
(Opponent 1) Sandhofer Strasse 116  
68305 Mannheim (DE)

**Representative:** Pfeifer, Hans-Peter  
Durm & Partner  
Patentanwälte  
Moltkestrasse 45  
76133 Karlsruhe (DE)

**Appellant:** ARKRAY, Inc.  
(Opponent 2) 57, Nishiaketa-cho  
Higashikujo  
Minami-ku  
Kyoto-shi  
Kyoto 601-8045 (JP)

**Representative:** HOFFMANN EITLE  
Patent- und Rechtsanwälte  
Arabellastrasse 4  
81925 München (DE)

**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
7 January 2013 concerning maintenance of the  
European Patent No. 1394535 in amended form.

**Composition of the Board:**

**Chairman:** A. Klein  
**Members:** A. Hornung  
B. Müller

## Summary of Facts and Submissions

- I. The two opponents and the patentee appealed against the interlocutory decision of the opposition division maintaining European patent No. 1394535 in amended form.

Oppositions were filed against the patent as a whole and based on the grounds of Article 100(a), together with Articles 54(1) and 56 EPC, and on Articles 100(b) and (c) EPC.

The opposition division held that the patent as amended according to the fourth auxiliary request then on file, identical to the fifth auxiliary request now on file, met the requirements of the EPC.

- II. Oral proceedings before the board were held on 9 April 2014.
- III. Together with the grounds of appeal, the patentee requested that the decision of the opposition division be set aside and that the patent be maintained as granted (main request) or, alternatively, maintained upon the basis of any of the auxiliary requests 1 to 5, filed under cover of a letter dated 16 May 2013.

The opponents requested that the decision of the opposition division be set aside and that the patent be revoked.

- IV. Independent claim 1 according to the patentee's main request reads as follows:

"1) A meter comprising:  
a housing (81);  
a display (82) for displaying results;

a slot for insertion of a disposable electrochemical sensor for detection and/or quantification of analyte in a liquid sample; and

a timing circuit adapted to control measurement of current indicative of analyte in the sample following detection of sample application to the sensor when the sensor is inserted in the meter,

characterized in that the timing circuit is further adapted to cause the measurement of current to occur at a time 15 seconds or less after the detection of sample application."

Claims 2 to 4 are dependent on the above independent claim 1.

Independent claims 1 according to the patentee's auxiliary requests (AR 1 to AR 5) differ from the above independent claim 1 of the main request in that the time periods specified in the respective characterizing portions read as follows:

AR 1: "... to occur at a time less than 10 seconds after the detection of sample application."

AR 2: "... to occur at a time 4 to less than 10 seconds after the detection of sample application."

AR 3: "... to occur at a time 8 seconds or less after the detection of sample application."

AR 4: "... to occur at a time 4 to 8 seconds after the detection of sample application."

AR 5: "... to occur at a time 5 seconds or less after the detection of sample application."

V. The following document will be referred to in the present decision:

D10: US 5,366,609

## **Reasons for the Decision**

### 1. Order of dealing with the claim requests

The claim requests differ from one another only in respect of the time range in which the measurement is to occur. Auxiliary request 5 is the claim request which was found allowable by the opposition division. Since claim 1 of this request also comprises the shortest upper limit of the time range, i.e. 5 seconds, which value is included in the claimed time ranges of all the requests, the board, in agreement with the parties at the oral proceedings, started patentability assessment with auxiliary request 5.

### 2. Auxiliary request 5

#### 2.1 Proper construction of claim 1

During oral proceedings, a debate on how to interpret the features relating to the timing circuit of the claimed meter took place.

Claim 1 is directed to a meter which, amongst others, is defined by reference to a sample, to an analyte in the sample and to a sensor for detecting the analyte in the sample. However, none of the sample, the analyte or the sensor belongs to the claimed meter. It follows that no precise limitation of the claimed scope can be inferred therefrom.

Claim 1 in particular recites a timing circuit defined by the following functional feature:

"a timing circuit adapted to control measurement of a current indicative of analyte in the sample following detection of

sample application to the sensor when the sensor is inserted in the meter".

It is however obscure how the timing circuit is specifically adapted to ensure that the measured current is indicative of analyte. Claim 1 remains silent about any feature providing a reliable measure of an analyte in a sample. A timing circuit is an electronic circuitry whose electronic output does generally not have any effect on whether the current to be measured is actually a faithful indication of any property of the sample. The nature of the current generally depends only on the physical circumstances under which the current has been generated, i.e. on the sensor generating the current and on the item to be sensed by the sensor. Therefore, the timing circuit according to claim 1 is to be understood as a general timing circuit which is adapted to control the measurement of any current through a sample inserted in the slot, be it actually indicative of analyte in the sample or not.

## 2.2 Closest prior art

The parties did not dispute that D10 may be considered as being the closest prior art document.

D10, with reference to figures 1 and 3, discloses a biosensing meter (10) comprising a housing, a display (12), a slot (16) for insertion of an electrochemical sensor (18), a microprocessor (59) comprising a RAM and further electronic circuitry associated with the microprocessor, such as an excitation voltage source (44) and a bus (58). The meter of D10 is used in combination with a removably pluggable ROM key (30) comprising a programmable ROM chip (32). See column 4, line 29 to column 5, line 18.



Upon application of a drop of blood to a sample strip inserted in the meter, an immediate increase in current is sensed by the meter (column 6, lines 45-51). The microprocessor of the meter and its associated electronic circuitry, in combination with data read from the programmable ROM chip, provides overall control of the operation of the meter and enables the meter to adjust its measurement parameters (column 5, lines 3-13). These measurement parameters allow to adjust the commencement and duration of the incubation time  $t_i$  and the commencement, delay and duration of the measurement time  $t_m$  (column 6, line 52 - column 7, line 65; figures 4 and 6). The microprocessor and its associated electronic circuitry thus correspond to a timing circuit controlling and causing the measurement of current to occur at a certain point in time after detection of sample application to a sensor inserted in the slot of the meter.

The biosensing meter of D10 is specifically adapted to be employed under various measurement procedures due to its use of a "removably pluggable memory module" (column 1, lines 6-28). Whilst a specific example is shown in relation to figure 4 where a measurement period starts at 9 seconds after sample application, D10 remains silent about whether the microprocessor is adapted to cause the measurement of current to occur at a time 5 seconds or less after the detection of sample application, as set out in claim 1.

It follows that D10 discloses all the features of claim 1 except for the actual point in time at which the measurement of current is caused by the microprocessor to occur.

### 2.3 Obviousness

The effect of the distinguishing feature of claim 1 is to provide a range of concrete numerical values for the points

in time at which the timing circuit causes the measurement of current to occur.

The objective technical problem to be solved can therefore be seen as implementing a timing circuit having a concrete point in time at which the timing circuit causes the measurement of current to occur.

Deciding whether the claimed solution to this problem is obvious or not boils down to the question of whether the skilled person, while putting the meter of claim D10 into practice, will arrive or not at a value falling within the claimed range. A similar approach for assessing obviousness was taken in the decisions T 408/12, point 7.3 of the reasons, and T 315/97, point 3.3.1 of the reasons.

While putting the embodiment of D10 into practice, the skilled person will necessarily have to fill the gap in the disclosure of D10 in selecting a concrete timing circuit composed of a microprocessor with its electronic circuitry and its inherent capability of causing the measurement of current to occur within a certain time range.

According to the embodiment of D10, the timing circuit is enabled to cause an excitation voltage source to apply excitation voltages at various levels and various time ranges (column 6, line 35 - column 7, line 65). Exemplary time ranges which the timing circuit of D10 is able to handle are the ranges of milliseconds and seconds (see column 6, lines 61-65, in combination with the time scale of figure 5; see column 7, lines 4-25, in combination with the time scale of figure 4). The claimed time range, i.e. "within 5 seconds", is included in the time ranges disclosed in D10.

From the disclosure of D10 it appears that the microprocessor and its associated electronic circuitry are of a conventional

nature. There is no indication in D10 that the skilled person must be careful in selecting a specific microprocessor and associated electronic circuitry which would not be adapted to cause the measurement of current to occur within a particular time range.

On the contrary, as convincingly demonstrated by the opponent 1 at the oral proceedings, it is apparent from the disclosure of D10, that the device of D10 is intended for the use of a large variety of sensors having different sensing characteristics and measurement procedures. D10 explicitly relates to "the problem of enabling a biosensing meter to adapt to substantially revised test protocols and procedures without the need for redesign of the electronics or meter" (column 3, lines 11-17). The object of the invention of D10 consists in providing a biosensor meter that "enables substantial reconfiguration of test procedures and parameters employed by the meter", in particular, that "enables threshold potentials, test times, delay periods ... to be inserted and/or altered" (column 3, lines 21-27).

It is obvious that the skilled person, when putting the meter of D10 into practice by following the teaching of D10, will implement a versatile timing circuit composed of a microprocessor and its associated electronic circuitry which are adapted to cause the measurement of current to occur within the broadest possible range of time.

Indeed, D10 aims at supplying a meter which can be used with a large variety of sensors and different test procedures. The solution taught in D10 is to provide a timing circuit which is able to read and adequately handle various threshold potentials, test times and delay periods, parameters which are delivered by a programmable ROM to the timing circuit via a data bus. The skilled person, seeking to go on using an existing meter despite revised threshold potentials, test

times and delay periods, requires the largest possible freedom of action to operate the meter. Therefore, the actual timing circuit, selected when putting into practice the device of D10, would obviously have the potential of handling measurements of current to occur within a reasonably broad range of time. No inventive step can be seen in including in this reasonably broad time range the claimed value of 5 seconds after the detection of sample application, the less so since reducing measurement time must be considered as an obvious desire of the user, as put forward by both opponents in their respective statements of the grounds of appeal. On the contrary, implementing a timing circuit in the meter of D10 which is *not* capable of handling a measurement of current within the claimed time range would appear to be surprising and to require deliberate modifications of the normal capabilities of a conventional timing circuit.

In view of the foregoing, the subject-matter of claim 1 lacks an inventive step in view of the disclosure of D10 (Article 56 EPC).

2.4 The patentee presented the following counter-arguments:

2.4.1 For the patentee, claim 1 defines a timing circuit which is specially adapted, firstly, to control the measurement of current being *indicative of analyte in the sample* and, secondly, to cause the measurement *to occur* within 5 seconds after sample detection. In the patentee's view, this means that the claimed timing circuit is *not only suitable for* fulfilling these two functions but that it effectively realizes the two corresponding requirements, thereby representing two concrete technical features of the claimed meter.

The patentee further explains that in the measurement procedure of D10, an incubation period of 9 seconds is

required during which no measurement of current occurs. Even more importantly, D10 does not disclose a measurement time at all of a "current indicative of analyte", but only the measurement of current at a plurality of points in time "to determine the level of the Cottrell curve", which "level is indicative of the [analyte] concentration" (see column 5, lines 52-65; figure 4). For the patentee, "none of the individual measurements shown in figure 6, when taken alone, is a measurement of current indicative of analyte" (see also the letter of the patentee, dated 16 May 2013, point 4.1.5).

Therefore, based on the teaching of D10, the skilled person would have no reason to expect to obtain reliable results of the current indicative of analyte within short measurement periods. In the absence of any hint about the feasibility of making faster measurements of current indicative of analyte, the skilled person would have no motivation to modify the timing circuit of D10 as defined in claim 1.

This argument is not found convincing by the board since it is based on the assumption that the current measured by the meter of claim 1 is necessarily a current indicative of an analyte and that such a measurement effectively occurs within 5 seconds of the detection of the analyte in the sample. This assumption is not shared by the board as explained in point 2.1 above. Upon request by the board during oral proceedings to explain how the timing circuit is specially adapted to ensure that the measured current is really indicative of the amount of analyte in the sample, the patentee did not provide any relevant explanation.

- 2.4.2 The patentee acknowledged that D10 discusses the possibility of adapting a meter to work with different sensors and that D10 discloses a meter which enables threshold potentials, test times and delay periods to be set and/or altered. However, D10 does not indicate that any of the stages of the

measurement cycle shown in figure 4 can be dispensed with or that any of these times or periods can be modified (see the patentee's letter dated 30 October 2013, point 5.3). The patentee, therefore, concluded that the skilled person would have no reason to modify the timing circuit of D10 as defined in claim 1.

The board cannot see which concrete modifications of the timing circuit of D10 are required to arrive at the claimed subject-matter. Indeed, as explained in point 2.3 above and stressed by the board in the course of the oral proceedings, the question is not about how to modify the timing circuit of D10 but about how to fill the gap in the disclosure of D10 concerning the capability of the timing circuit to receive a time parameter which is within 5 seconds of a starting signal, to control the voltage source correspondingly and to read the resulting current. The board came to the conclusion that it would be obvious for the skilled person to implement in D10 a timing circuit being capable of handling the largest variation of time ranges so as to provide complete freedom of action to the skilled person should he/she want to use the existing meter in relation to a new test procedure, for instance, in case that sensors allowing for faster measurements become available. Therefore, the board sees no need for the skilled person to have actual knowledge of a prior art sensor achieving reliable results within 5 seconds, in order to envisage this delay value when putting the teaching of D10 into practice.

3. Main request and auxiliary requests 1 to 4.

The subject-matter of claim 1 of the main request and of the auxiliary requests 1 to 4 lacks an inventive step with respect to the disclosure of D10 for reasons corresponding to those given for the fifth auxiliary request.

In particular, when putting the device of D10 into practice, the board is of the view that the skilled person would implement a conventional timing circuit capable of handling the various time ranges as claimed in the main request and in any of the auxiliary requests 1 to 4, which all include the value of 5 seconds set out in auxiliary request 5.

At the invitation of the board during oral proceedings to present counter-arguments in respect of inventive step of the main request and the auxiliary requests 1 to 4, the patentee replied that it had no additional arguments to those already presented in favour of the fifth auxiliary request.

## Order

### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



M. Kiehl

A. Klein

Decision electronically authenticated